

XIV. SUMMARY OF SAFETY AND EFFECTIVENESS



510(k) SUMMARY OF SAFETY AND EFFECTIVENESS COATED STERILE LATEX POWDER-FREE SURGICAL GLOVES

Manufacturer: Allegiance Healthcare Sdn. Bhd.
Plot 87, Kampung Jawa
11900 Bayan Lepas
Penang, West Malaysia

Regulatory Affairs Contact: Erica Sethi
Allegiance Healthcare Corporation
1500 Waukegan Road, MP-WM
McGaw Park, IL 60085

Telephone: (847) 785-3337

Date Summary Prepared: 6/16/99

Product Trade Name: Undetermined

Common Name: Surgical Glove

Classification: Glove, Surgeon's

Predicate Devices: Ultrafree Sterile Latex Powder-Free Surgical Gloves

Description: Coated Sterile Latex Powder-free Surgical gloves are formulated using natural rubber latex and are coated with a nitrile coating. These are offered powder-free and sterile.

Intended Use: Coated Sterile Latex Powder-Free Surgical Gloves are intended for use in environments within hospitals and other healthcare facilities. The gloves are appropriate for use during invasive and non-invasive medical procedures requiring sterility. They are intended to be worn by operating room personnel to protect a surgical wound from contamination.

Substantial Equivalence: Coated Sterile Latex Powder-Free Surgical Gloves are substantially equivalent to Ultrafree Sterile Latex Powder-Free Surgical Gloves in that they provide the following characteristics:

- same intended use
- same sizes, configuration, packaging
- both made of natural rubber latex
- same tensile strength and thickness profiles

Summary of Testing:

<u>Test</u>	<u>Result</u>
Systemic Toxicity	Gloves do not elicit any toxic reactions to acute application.
Intracutaneous Reactivity	Gloves show no reactivity.
Guinea Pig Maximization	Gloves do not display any potential for irritation.
Ultimate Elongation & Tensile Strength	Gloves meet or exceed requirements for rubber surgical gloves per ASTM D3577-99.
Barrier Defects	Gloves exceed requirements per 21 CFR §800.20, AQL = 2.5.
Data/Test Method	Gloves meet powder level requirements for "Powder Free" designation using ASTM Standard D6124-97-Standard test method for residual powder on medical gloves. Results generated values below 4 mg of residual powder per glove.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 1999

Ms. Erica Sethi
Manager, Regulatory Affairs
Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085

Re: K992171
Trade Name: Coated Sterile Latex Powder-Free Surgical
Gloves with Protein Content Labeling Claim (50
micrograms or less)
Regulatory Class: I
Product Code: KGO
Dated: August 18, 1999
Received: August 19, 1999

Dear Ms. Sethi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

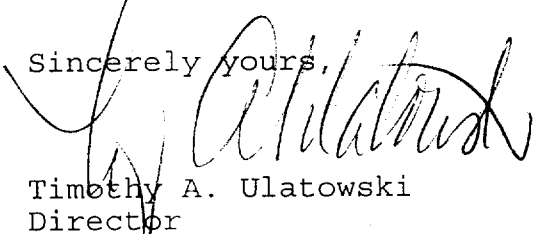
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4690. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 99 2171



Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1500
FAX: 847.785.2460

Page 1 of 1

Applicant: Allegiance Healthcare Corporation

510(k) Number:

Device Name: Coated Sterile Latex Powder-Free Surgical Gloves
With Protein Content Labeling Claim (50 micrograms or less)

Indications For Use: These gloves are intended for use in environments within hospitals and other healthcare facilities. The gloves are appropriate for use during invasive as well as non-invasive medical procedures requiring sterility. They are intended to be worn by operating room personnel to protect a surgical wound from contamination.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

or

Over-The Counter Use ☒

(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number

K 992171